

## REMARKS

Claims 1-19 are currently pending. Claims 1-19 stand rejected under 35 U.S.C. § 103(a) as being obvious in light of multiple references. No amendments are proposed herein.

### 35 U.S.C. § 103(a) Rejections

Claims 1-19 stand rejected under 35 U.S.C. § 103(a) as being obvious and unpatentable in light of the combination of Raijmakers et al. (U.S. Pat. No. 5,998,639), Simoons (U.S. Pat. No. 4,154,820), Raveendranath et al. (U.S. Pat. No. 5,288,717), Shah et al. (U.S. Pat. No. 6,525,039), Bender et al. (U.S. Pat. No. 5,998,638), and Kong et al. (U.S. Pat. No. 6,458,778). These rejections are maintained from the previous Office Action and Applicant respectfully traverses the rejections.

In order to maintain a *prima facie* obviousness rejection certain criteria must be met. In particular:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

*See, M.P.E.P. §2142, citing In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)*(emphasis added). The references and the art do not provide a motivation to combine the reference teachings to make or arrive at the combination proffered by the Action. The lack of motivation precludes a *prima facie* obviousness rejection. In addition, the references fail to teach or suggest all of the recitations of the claims. This failure also precludes a *prima facie* obviousness rejection. Claims 1-19 are allowable over the 35 U.S.C. § 103(a) rejections.

The Action indicates that the motivation to make a mixture of sulfated estrogens is based upon the use of mixtures of conjugated estrogens in the treatment of estrogen deficiency. *See, Action at p. 4*. However, a desired use of mixtures of conjugated estrogens in the treatment of estrogen deficiency does not motivate a process for arriving at a mixture of conjugated estrogens, let alone the processes recited in the claims of the present application. A person of skill in the

art, looking at the cited references, would not be motivated to develop a new process for forming mixtures of conjugated estrogens because Raijmakers et al. discloses methods for making such mixtures. Thus, in light of the prior art, there is no motivation to develop another process to make a mixture of sulfated estrogens because the prior art already discloses a process that achieves the alleged motivation. The disclosed process, however, does not make obvious the claimed processes.

The Action also indicates that the motivation to use or alter the process taught by Shah and Raveendranath to arrive at the processes recited by the claims at issue is, in part, based on the “reasonable expectation that in combination each individual alkali metal salt would undergo sulfatation with the production of a mixture comprising sulfates of each alkali metal salts reacted.” However, neither Shah nor Raveendranath acknowledge this “reasonable expectation.” Raveendranath discloses the sulfatation of an alkali metal salt of 8,9-dehydroestrone alone, not in combination with other alkali metal salts. Shah also fails to lend any support to the “reasonable expectation” that a combination of alkali metal salts could undergo sulfatation at the same time. Further, if such an expectation was indeed reasonable, it is more than likely that Shah or Raveendranath would have disclosed such an expectation. In addition, no other source is cited for this “reasonable expectation.” The only reference available which teaches or suggests that a sulfur trioxide complex can be reacted with a mixture of more than one alkali metal salts of estrogens to provide a mixture of sulfated alkali metal salts of estrogens is the Specification. A *prima facie* case of obviousness, however, must be based on the knowledge in the art, and not on the applicant’s disclosure. *See, In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). The “reasonable expectation” alleged in the Action is not based on the knowledge in the art, but rather on the Specification. Thus, a *prima facie* obviousness rejection is not supported.

Additional motivation for the combination of references allegedly comes from the supposed “desire to obtain a one pot mixture of said alkali metal salts of estrogen sulfates.” *See, Action* at p. 4. However, even if one of skill in the art was motivated to obtain a one pot mixture, there is no motivation to combine the cited references to arrive at the processes recited in the claims because the references fail to provide the alleged “reasonable expectation” and they fail to teach or suggest all of the recitations of the claims.

The references alone fail to teach or suggest the processes recited in the claims. Any desire in the art to use mixtures of conjugated estrogens in the treatment of estrogen deficiency may be resolved using mixtures provided by the processes of Raijmakers et al. Thus, there is no desire or motivation, in the art or in the references themselves, to arrive at new processes for the production of a mixture of sulfated estrogens. This lack of motivation precludes a *prima facie* obviousness rejection. In addition, the alleged motivation provided by the “reasonable expectation” is based upon the Specification and not by the cited references. The motivation to combine references to make obvious a claim must not be based on the Specification. *See, In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Claims 1-19 are also nonobvious because the cited references fail to teach or suggest all of the recitations of the claims. In particular, the cited references fail to teach or suggest the recitations of independent Claims 1 and 15. Claims 1 and 15 are therefore nonobvious. *See, In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Claims 2-14 and 16-19, which depend from Claims 1 and 15 are also nonobvious because they depend from nonobvious independent claims. *See, In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988)(stating that if an independent claim is nonobvious under 35 U.S.C. § 103 then any claim depending therefrom is nonobvious); *see also*, M.P.E.P. § 2143.03.

Claim 1 specifically recites a process for the production of a mixture of sulfated estrogens, comprising, in part, “reacting a sulfur trioxide complex with a mixture of at least two alkali metal salts of estrogens.” None of the references propose such a reaction. Although Raijmakers et al. may propose the sulfatation of a single alkali metal salt, Raijmakers et al. does not propose reacting a sulfur trioxide complex with a mixture of at least two alkali metal salts. Thus, Raijmakers et al. does not teach or suggest at least one step recited in Claim 1, specifically “reacting a sulfur trioxide complex with a mixture of at least two alkali metal salts of estrogens.” Claim 1 is not obvious in light of Raijmakers et al. because a *prima facie* obviousness rejection is not supported unless all of the claim recitations are taught or suggested by the reference. *See, In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

The Action also admits that Raijmakers et al. and the other references fail to establish a *prima facie* obviousness rejection. In particular, the Action states: “Unlike, Raijmakers et al. Kong and Bender, the claimed process recites sulfatation of the alkali metal salts of estrogens or

production of the alkali metal salts of estrogens followed by sulfatation.” *See, Action* at p. 3. This admission alone precludes an obviousness rejection under 35 U.S.C. § 103(a).

The Action attempts to support the obviousness rejection by relying upon the holding of *Ex parte Rubin*, arguing that the reversal of the steps in a multi-step process is not a patentable modification absent unexpected or unobvious results. This argument is based on the assumption that all of the steps in the process are taught or suggested by the prior art. If all of the steps were not taught, then the new process would not be obvious. According to the M.P.E.P., *Ex parte Rubin* held that reversing the order of prior art process steps was *prima facie* obvious. *See, M.P.E.P.* § 2144.04 (*citing, Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render *prima facie* obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps)). The processes recited in the claims of the pending application, however, do not reverse the order of prior art process steps because none of the cited references teach or suggest all of the recitations of the claims.

The Action alleges that “the production of a mixture synthetic conjugated estrogens sulfate salt utilized in the composition of Simoons by reversal of the steps taught by Raijmakers et al. utilizing the process taught by Shah and Raveendranath would be *prima facie* obvious.” *See, Action* at p.3 (emphasis added). Thus, the rejection cited by the Action is based upon Raijmakers et al. teaching all of the steps recited in Claim 1. Raijmakers et al., however, does not teach or suggest “reacting a sulfur trioxide complex with a mixture of at least two alkali metal salts of estrogens” as recited in Claim 1. The Action also admits that Raijmakers et al. fails in this respect. Since Raijmakers et al. fails to teach all of the steps recited in Claim 1, the holding of *Ex parte Rubin* does not support a *prima facie* obviousness rejection because the steps of the process recited in Claim 1 are not known in the art. The failure of the cited references to teach or suggest all of the recitations of Claim 1 precludes a *prima facie* obviousness rejection of Claim 1.

For at least the foregoing reasons, Claim 1 is allowable over the 35 U.S.C. § 103(a) rejection. Claims 2-14 depend from Claim 1 and are also allowable because a dependent claim of a nonobvious independent claim is also nonobvious. *See, In re Fine*, 837 F.2d 1071, 5

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U.S.P.Q.2d 1596 (Fed. Cir. 1988)(stating that if an independent claim is nonobvious under 35 U.S.C. § 103 then any claim depending therefrom is nonobvious); *see also*, M.P.E.P. § 2143.03.

Independent Claim 15 also recites a process for the production of a composition of a mixture of sulfated estrogens, wherein one step in the process includes “reacting sulfur trioxide-trimethylamine with the mixture of alkali metal salts of estrogens.” As with Claim 1, the references fail to teach or suggest all of the recitations of Claim 15 for the same reasons as recited herein. Claim 15 is therefore allowable over the 35 U.S.C. § 103(a) obviousness rejection. Claims 16-19 are also allowable as dependent claims of a nonobvious independent claim. *See, In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988)(stating that if an independent claim is nonobvious under 35 U.S.C. § 103 then any claim depending therefrom is nonobvious); *see also*, M.P.E.P. § 2143.03.

## CONCLUSION

The concerns of the Examiner addressed in full, Applicants respectfully request withdrawal of the outstanding rejections and the issuance of a Notice of Allowance forthwith. The Examiner is encouraged to direct any questions regarding the foregoing to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,



Devin R. Jensen  
Registration No. 44,805

## CERTIFICATE OF EXPRESS MAILING

"Express Mail" mailing label number: EV318416951US Date of Deposit: December 22, 2003  
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Sloan Smith  
Sloan Smith